510(k) Summary

K061565

Common/Usual Name: Intravascular diagnostic catheter

Product Trade Name: Langston™ Dual Lumen Catheter

Classification Name: Diagnostic intravascular catheter; 21 CFR 870.1200; DQO

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Establishment Registration: 2134812

AUG 0 2 2006

Contact: Julie Tapper
Regulatory Affairs Associate
Phone (763) 656-4228
Fax (763) 656-4253

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description: The Vascular Solutions Langston™ Dual Lumen Catheter is intended for use as a pressure measurement catheter and for delivery of contrast media during angiographic studies. The Langston catheter consists of the Merit Medical Softouch Diagnostic Intravascular Catheter (K943739) as the inner lumen and an extruded outer lumen designed by Vascular Solutions. The inner lumen and hub assembly are purchased from Merit Medical in a non-sterile state. The pigtail catheter and outer lumen are joined together using an adapter junction placed near the proximal end of the pigtail catheter. The adapter junction incorporates a side port fitted with a stopcock/tube assembly for fluid flow and pressure measurement within the outer tube. The distal end of each lumen is perforated with side holes to allow pressure measurement simultaneously. The Langston catheter is deployed through standard guide catheters and will accommodate standard 0.038″ diameter guidewires.

Intended Use: The Langston™ Dual Lumen Catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. This type of pressure measurement is useful in determining transvalvular, intravascular and intraventricular pressure gradients.

Summary of Non-Clinical Testing: Testing included assessment of the physical properties of the device and its ability to achieve its intended use. The results of the tests confirmed the suitability of the device for its intended use.

Predicate Devices: The Langston 7F/5F dual lumen catheter is substantially equivalent to the Langston 8F/5F (K041909), 7F/4F (K050168), and 6F/4F (K051395) dual lumen catheters.

Conclusions: The Langston 7F outer lumen and 5F inner lumen is substantially equivalent to the currently marketed Langston catheters, based on a comparison of the indications for use, construction materials, catheter dimensions, injection pressure ratings, and sterilization methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

Vascular Solutions, Inc.
c/o Ms. Julie Tapper
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K061565
Langston™ Dual Lumen Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: June 1, 2006
Received: June 5, 2006

Dear Ms. Tapper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K061565

Device Name: Langston™ Dual Lumen Catheter

Indications for Use: The Langston™ Dual Lumen Catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. This type of pressure measurement is useful in determining transvalvular, intravascular and intraventricular pressure gradients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE, IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Whitney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061565